Breast Cancer
IDGN-BC-A04

I. INCLUSION AND EXCLUSION CRITERIA

INCLUSION CRITERIA

	Yes	No
1. Subject is diagnosed by histopathology with:		
a. Ductal adenocarcinoma invasive and / or in situ, including comedo, inflammatory, medullary, mucinous, papillary, scirrhous and tubular subtypes.	☐	☐
b. Lobular adenocarcinoma invasive and / or in situ.	☐	☐
c. Paget's disease with / without invasive ductal or intraductal component.	☐	☐
2. Subject is female.	☐	☐
3. Subject is of Ashkenazi Jewish origin, as declared by the subject.	☐	☐
4. Subject or subject's legal representative has signed the informed consent form.	☐	☐

EXCLUSION CRITERIA

	Yes	No
1. Subject is diagnosed with the following breast disease:		
a. Non-adenocarcinoma epithelial tumor (e.g. squamous cell carcinoma).	☐	☐
b. Non-epithelial tumor (e.g. lymphoma).	☐	☐
c. Cystosarcoma phyllodes.	☐	☐
2. Li-Fraumeni syndrome-inherited germline mutation in the tumor suppressor gene p53.	☐	☐
3. A history of ionizing irradiation to the chest region (e.g. treatment for Hodgkin's disease).	☐	☐
4. Subject is a known carrier of a blood transmitted infectious disease or suffers from conditions in which phlebotomy is contra-indicated.	☐	☐
5. Subject's **current** white blood cell (WBC) count is less than 2000 cells/mm^3.	☐	☐

Subject is eligible for the study if all **INCLUSION** criteria are **YES** and all **EXCLUSION** criteria are **NO.**

INVESTIGATOR'S STATEMENT CONCERNING DATA VERIFICATION

I have verified the data entered in the Case Report Form and have determined that it is complete, accurate and compatible with the source documents.

Investigator's name (printed)	Investigator's signature	☐☐ / ☐☐ / ☐☐
		Day / Month / Year

Where appropriate mark like this ☒ (not like this ☑)

SUBJECT BARCODE STICKER

Breast Cancer

IDGN-BC-A04

II. DEMOGRAPHICS

1. Year of birth: ☐☐☐☐

2. Country of birth: _____

3. Year of immigration: ☐☐☐☐

4. Height*: ☐☐☐ cm

5. Weight at time of diagnosis*: ☐☐☐ kg

* If measurements cannot be carried out, subject declaration is sufficient.

III. FAMILY HISTORY

1. Maternal		**2. Paternal**	
	Country of birth		Country of birth
1.1 Mother:	_____	2.1 Father:	_____
1.2 Grandfather:	_____	2.2 Grandfather:	_____
1.3 Grandmother:	_____	2.3 Grandmother:	_____
	Yes ☐ No* ☐		Yes ☐ No* ☐
1.4 Mother is alive		2.4 Father is alive	
*If not, specify age at death:	☐☐	*If not, specify age at death:	☐☐

SUBJECT BARCODE STICKER

Breast Cancer

IDGN-BC-A04

III. FAMILY HISTORY (Cont.)

3. Were any other malignancies diagnosed in the family (including grandfather, uncles and aunts)? **Yes*** ☐ **No** ☐

*If yes, fill the tables indicating cancer type and specifying approximate age at onset, **only for those relatives with cancer:**

Female family members:

	Breast cancer		Ovarian cancer		GI cancer		Other	
	Yes	Age	Yes	Age	Yes	Age	Specify	Age
Mother	☐		☐		☐			
Mother's mother	☐		☐		☐			
Mother's sister	☐		☐		☐			
Mother's sister	☐		☐		☐			
Father's mother	☐		☐		☐			
Father's sister	☐		☐		☐			
Father's sister	☐		☐		☐			
Sister	☐		☐		☐			
Sister	☐		☐		☐			

Male family members:

	Prostate cancer		GI cancer		Other	
	Yes	Age	Yes	Age	Specify	Age
Father	☐		☐			
Father's father	☐		☐			
Father's brother	☐		☐			
Mother's father	☐		☐			
Mother's brother	☐		☐			
Brother	☐		☐			

SUBJECT BARCODE STICKER

Breast Cancer

IDGN-BC-A04

IV. CLINICAL CHARACTERISTICS

1. Date of diagnosis (month / year): ☐☐ / ☐☐☐☐

2. Stage at diagnosis (TNM classification):

Tx ☐ T0 ☐ Tis ☐ T1 ☐ T2 ☐ T3 ☐ T4 ☐

Nx ☐ N0 ☐ N1 ☐ N2 ☐ N3 ☐

Mx ☐ M0 ☐ M1 ☐

3. Mark main histologic type:

DCIS[1]	Ductal invasive	Ductal other	LCIS[2]	Lobular invasive	Paget's disease	Other
☐	☐	☐	☐	☐	☐	☐

	positive	negative	unknown
4. Estrogen receptor status:	☐	☐	☐
5. Progesterone receptor status:	☐	☐	☐

6. Reproductive and menstrual history:

Age at menarche: ☐☐ Age at menopause: ☐☐

Total no. of full term pregnancies: ☐☐ Age at first full term pregnancy: ☐☐

	Yes	No	Unknown
7. Did the patient use oral contraceptives during the 10 years prior to the diagnosis of the cancer?	☐	☐	☐
8. Did the patient use HRT[3] during the 5 years prior to the diagnosis of cancer?	☐ *	☐	☐
***If yes, specify number of years:** ☐☐			
9. Did the patient have a history of a benign breast disease?	☐	☐	☐
10. Was the patient diagnosed as having a BRCA1 mutation?	☐	☐	☐
11. Was the patient diagnosed as having a BRCA2 mutation?	☐	☐	☐

12. Did the disease recur? Yes ☐ * No ☐

***If yes, specify date (month / year):** ☐☐ / ☐☐☐☐

13. Smoking history - no. of years: ☐☐ no. of packs per day: ☐☐

[1] DCIS – Ductal carcinoma in situ.
[2] LCIS – Lobular carcinoma in situ.
[3] HRT – Hormonal replacement therapy.

SUBJECT BARCODE STICKER

Breast Cancer

IDGN-BC-A04

IV. CLINICAL CHARACTERISTICS (cont.)

14. Was the patient diagnosed with any additional malignancies?	**Yes**	**No**	**Unknown**
Contralateral breast cancer	☐	☐	☐
Ovarian cancer	☐	☐	☐
Other cancer, specify: _____			

15. Specify patient's other chronic diseases: _____

_____

_____

V. MEDICATIONS

	Yes	**No**
1. Did or does the patient receive adjuvant Tamoxifen therapy?	☐*	☐
***If yes, specify number of years:** ☐☐		
***Were there adverse reactions associated with Tamoxifen therapy?**		
Endometrial hyperplasia / Neoplasia	☐	☐
Deep vein thrombosis / Pulmonary embolism	☐	☐
Ovarian cysts	☐	☐

2. For advanced disease - If the patient was treated for advanced disease please fill the table regarding drug efficacy:

	1st line				**2nd line**			
Drug / drug combination	**Complete response**	**Partial response**	**Stable disease**	**Unknown**	**Complete response**	**Partial response**	**Stable disease**	**Unknown**
Adriamycin	☐	☐	☐	☐	☐	☐	☐	☐
Paclitaxel / Docetaxel	☐	☐	☐	☐	☐	☐	☐	☐
Vinorelbine	☐	☐	☐	☐	☐	☐	☐	☐
Adriamycin+Paclitaxel / Docetaxel	☐	☐	☐	☐	☐	☐	☐	☐
CAF[1]	☐	☐	☐	☐	☐	☐	☐	☐
5-FU[2] as single agent	☐	☐	☐	☐	☐	☐	☐	☐
Other, specify: _____	☐	☐	☐	☐	☐	☐	☐	☐

[1]CAF - Cyclophosphamide, adriamycin, fluorouracil [2] 5-FU - Fluorouracil

SUBJECT BARCODE STICKER

V. MEDICATIONS (cont.)

3. Side effects – if the patient was treated with chemotherapy, mark the appropriate boxes:

	5 - FU single agent	Vinorelbine	CAF	Adriamycin	Paclitaxel/Docetaxel
Never treated	☐	☐	☐	☐	☐
Treated without significant adverse reaction	☐	☐	☐	☐	☐
Grade 4 vomiting[1]	☐	☐	☐	☐	☐
Grade 4 mucositis[2]	☐	☐	☐	☐	☐
Grade 4 diarrhea[3]	☐	☐	☐	☐	☐
Grade 3-4[4] neutropenia	☐	☐	☐	☐	☐
Hand-foot syndrome[5]	☐	☐	☐	☐	☐
Hypersensitivity reaction[6]	☐	☐	☐	☐	☐
Peripheral neuropathy	☐	☐	☐	☐	☐

[1] National Cancer Institute (NCI) toxicity criteria grade 4 stomatitis is defined as requiring enteral or parenteral support. NCI toxicity criteria grade 4 gastritis is defined as life threatening bleeding requiring emergency surgery. NCI toxicity grade 4 colitis is defined as perforation or requiring surgery or toxic megacolon.

[2] NCI toxicity criteria grade 4 vomiting is defined as requiring parental nutrition, intensive care admission or hemodynamic collapse.

[3] NCI toxicity criteria grade 4 diarrhea is defined as an increase of more than 10 stools daily, grossly bloody stools, or the need for parental fluid replacement therapy.

[4] NCI toxicity criteria grade 3 or 4 neutropenia is defined by a neutrophill count of less than 1000/microL.

[5] An erythematous, desquamative rash involving the hands and feet. The rash may be accompanied by tingling or painful hands and feet, swollen palms and soles, and phalangeal tenderness.

[6] Flushing, rush, hypotension, dyspnea, tachycardia, anaphylaxis.